

Docket No.: SYN-064 B

Applic. No. : 10/010,247 Confirmation No. 5785
Applicant : Juergen A. Kortenbach et al.
Filed : December 6, 2001
Title : Apparatus for the Endoluminal Treatment of
Gastroesophageal Reflux Disease (GERD)
Group Art Unit : 3731
Examiner : Bradford C. Pantuck

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Customer No. : 000044338

DECLARATION under 37 C.F.R. § 1.132

In order to assist in the prosecution of this application and in the traversal of the rejection of the claims by the Examiner, I, Juergen Kortenbach, do hereby declare as follows:

I am a citizen of Canada. I am a mechanical engineer specializing in biomedical engineering and materials sciences. I have a degree in Mechanical Engineering from the University of Waterloo in Canada and have 18 years of experience designing biomedical devices. I am a named inventor in over 65 patents. Significantly, I am the sole inventor of U.S. Patent No. 5,707,392 to Kortenbach.

I have read the specification and claims of U.S. Patent Application Serial No. 10/010,247 and the Final Office action

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dated January 25, 2005, in which claims were rejected as anticipated by my patent (5,707,392).

The Examiner is incorrect when he states that my hermaphroditic stamped forceps jaw invention "discloses a forceps capable of applying clips." My forceps cannot hold or advance a clip in the disclosed jaws 51, 151.

The Examiner suggests that each of the jaws 51, 151 has a channel 55 and "can easily imagine a c-shaped resilient clip that could fit within the forceps jaw of Kortenbach's device and be applied (slidingly) to tissue." This suggestion is incorrect.

While a groove can be placed in any forceps jaw or other foreign body extractor (or in any device for that matter), there is no reason to put a groove in my forceps invention as suggested by the Examiner.

Initially, I must point out that my forceps concept only dealt with a configuration for a cheaper, stamped, forceps cup design. In no way was it ever envisioned to be used with or to be associated with a surgical clip.

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Element 55 in my invention is not a groove as suggested by the Examiner. The only "groove" that can be imagined (and this is an assumption to which I disagree) is the space between tangs 58 and 60. This feature, however, is merely a space that results from a double walled transition from the tang area into the cup in a manner that is more rigid than having a single wall transition. This surmised groove is only in the tang area and is not in the jaw cup area. More importantly, this groove CANNOT be used for any kind of clip because a clip cannot be slid longitudinally in any useful distance due to the presence of axle 40 passing through mounting holes 68, 74.

In order to apply a clip as suggested by the Examiner, there has to be a locus of motion that allows the clip to move and be slideably applied. In the Examiner's handwritten addition to FIG. 2 of my patent, there is no space into which the clip can move slideably. Therefore, although the Examiner's illustration shows a clip that *might* be applied to living tissue, it cannot be slideably applied. In fact, the only slideable motion that can be imagined in such a construction is for the clip to fall slideably out of the jaw.

Significantly, the *imagined* clip shown in the Examiner's handwritten depiction in Attachment A requires material

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properties unknown to me (no materials existing can perform the functions supposed by the Examiner). Further, I know of no surgical clip that can survive the kind of implantation that is being suggested by the Examiner. In order to implant the suggested imagined clip of Attachment A with my forceps, the following movement of the jaws must occur:

- (1) the jaws must be closed during insertion;
- (2) the jaws must be opened at the implantation site; and
- (3) then, the jaws must be closed again to fasten the hypothetical clip.

I know of no clip that can:

- (1) be placed in the jaws;
- (2) be compacted down so that the jaws can close and can travel to the implantation site;
- (3) then be released to spring back open again so that the jaws and clip can travel around tissue to be clipped; and
- (4) then be compacted down again to perform the clipping that the imaginary "surgical clip" is supposed to accomplish.

One reason why the imagined clip does not and cannot exist is because the compacting down action in step 2 would lock the clip closed and would entirely prevent steps 3 and 4 from occurring.

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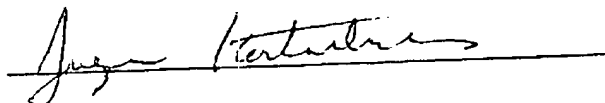
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Finally, the Examiner also states that each of the Kortenbach jaws 51 "has teeth capable of puncturing tissue, as shown in Figure 7." This conclusion is incorrect. The teeth of my forceps are not constructed to puncture tissue. Because my device is a merely a biopsy forceps, it is used to grasp. If the biopsy forceps punctured tissue as argued, the device would not be desirable to a physician because forceps jaws should grasp tissue securely with a minimum amount of crushing or damage to result in the best biopsy of tissue grasped.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: April 7, 2005

Signed:



Printed Name: Juergen Kortenbach